

REMARKS

With entry of the foregoing Amendment, claims 15 and 17-26 are currently pending in the application.

Claim 15 has been amended to more particularly point out that: 1) a cap-shaped piston section (8) is completely enclosed in an inert film (9'); 2) the uncoated sealing section and an entire edge region of the inert film (9') flatly abut in the working position against the syringe or carpule cylinder (1); 3) the uncoated sealing section has at least two continuous sealing lips (11) on its outer circumference spaced-apart by a continuous recess (12); and 4) that the annular continuous sealing zone (13) projects slightly radially beyond a surface of the entire edge region of the inert film (9'). Claim 19 has been amended to more particularly point out that the receiving cavity (6) has a bottom (6b) having a first diameter and a receiving orifice having a second diameter, the second diameter being larger than the first diameter. New claims 21-26 have been added to recite additional patentable features of the present invention.

Currently amended claims 15 and 19 and new claims 21-26 are at least supported by the original claims, Figs. 9-12 and specification paragraph [0004], [0005], [0012], [0044], [0045] and [0046], as amended. Accordingly, no new matter has been added and entry of the amendments is respectfully requested.

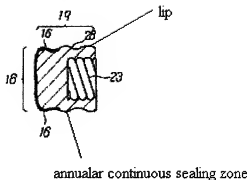
Telephone Interview

At the outset, Applicant wishes to thank Examiner Mehta for her time and the courtesy of a telephone interview with Applicant's representative, Mark Vogelbacker, on Thursday, October 2, 2008. During the interview, the undersigned requested clarification of the Examiner's objection to the specification and clarification of the Examiner's interpretation of Japanese Patent Application Publication No. 06-343677 (Moriaki), as stated in the outstanding Office Action.

Initially, Examiner Mehta stated that the objection to the specification can be overcome by amending the specification to include the currently recited claim language, which is supported at least by the drawings.

Further, as seen in the diagram below, the Examiner stated that she is interpreting the "hump" immediately to the right of the film (16) in Fig. 12 of Moriaki as equivalent to the annular continuous sealing zone of the present invention and the "hump" toward the right side of the body (19) in Fig. 12 of Moriaki as equivalent to the at least one lip of the present invention.

【圖 1 2】



In response to the interview, Applicant is submitting amendments to claims 15 and 19, and adding new claims 21-26, to further distinguish the present invention over the known prior art references. If Examiner Mehta determines that the above-cited amendments to claims 15 or 19 or new claims 21-26 are not patentable over the known prior art, Applicant requests that Examiner Mehta place a telephone call to Applicant's representative to discuss possible amendments to expedite prosecution.

Objections to the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter recited in previously presented claim 19. Applicant has amended the specification in accordance with the currently recited claims so as to provide proper antecedent basis and conform the specification to the drawings and the claims. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the objection to the specification.

Claim Objections

Claims 15 and 17-20 were objected to because the recitation in lines 15-16 of previously presented claim 15 lacked antecedent basis. In view of the Examiner's comments, Applicant has amended claim 15 to recite: "said annular continuous sealing zone (13) projecting slightly radially beyond a surface of the entire edge region of the inert film (9')." Therefore, the objection to the claims is moot and Applicant respectfully submits that the claims are in full compliance with the requirements. Applicant respectfully requests that the objection to the claims be reconsidered and withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 15 and 17-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Moriaki. The Examiner asserts that Moriaki discloses each and every element of these claims. The rejection of amended claim 15, and claims 17-20 depending therefrom, is respectfully traversed.

Referring to Figs. 6 and 12 and the machine English translation of Moriaki provided by the Examiner in the outstanding Office Action, Moriaki discloses an injector/vessel 1 having an injector barrel 2 with a proximal nozzle-head end 3 and a distal open end 14. As seen in Fig. 12, a drum section 19 is in the form of an elastic body having a proximal drug solution contact surface 18 and a distal end 28. A synthetic resin film layer 16 covers a portion of the proximal end of the drum section 19. However, the remaining or distal portion of the drum section 19 is not covered by the film layer 16. Further, an opening 23 is formed in the distal end of the drum section 19 and extends into the interior of the drum section 19. However, as seen in Fig. 12, the opening 23 does not extend into the region of the drum section 19 that is covered by the film layer 16.

Independent claim 15 of the present application is directed to a pharmaceutical piston stopper and recites, *inter alia*, as follows:

a cap-shaped piston section (8) completely enclosed in an inert film (9'), . . . the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the uncoated sealing section and an entire edge region of the inert film (9') flatly abutting in the working position against the syringe or carpule cylinder (1), the uncoated sealing section having at least two continuous sealing lips (11) on its outer circumference spaced-apart by a continuous recess (12), . . . with the receiving cavity (6) extending up into the piston section (8), and wherein the sealing section (10) has on its outer circumference an annular continuous sealing zone (13) directly adjacent to and directly adjoining the edge region of the inert film (9') enveloping the piston section (8) and abutting against an inside wall of the syringe or carpule cylinder (1), said annular continuous sealing zone (13) projecting slightly radially beyond a surface of the entire edge region of the inert film (9'). . .

Emphasis added]

Applicant respectfully submits that Moriaki fails to disclose each and every element of independent claim 15, as amended. Initially, Moriaki does not disclose, teach or even suggest an uncoated sealing section and an entire edge region of an inner film flatly abutting in the working position against the syringe or carpal cylinder. Instead, as seen in Fig. 12, Moriaki discloses a film layer 16 and a distal end 28, or an uncoated sealing section as asserted by the Examiner, with an edge region or side surface that is curvilinear in shape and includes spaced-apart “humps,” as the Examiner stated in the Interview Summary Form mailed on October 9, 2008. Thus, since the edge region of the film layer 16 of Moriaki has a wave-like shape, only a portion (i.e., the “humps”) of the film layers 16 of Moriaki abut against the injector barrel 2 in the working position, not the entire edge region as recited in amended claim 15.

Further, Moriaki fails to disclose a receiving cavity extending up into the piston section that is completely enclosed in the inert film. Instead, as seen in Fig. 12, the opening or receiving cavity 23 of Moriaki only extends into a portion of the distal end 28 of the drum section. Thus, the receiving cavity 23 of Moriaki does not extend up into the piston section covered by the film layer 16, as is recited in amended claim 15.

In addition, Moriaki fails to disclose an annular continuous sealing zone that projects slightly radially beyond a surface of the entire edge region of the inner film, as is recited in amended independent claim 15. Instead, the left most “hump” of the distal end 28 of the drum section 19 of Moriaki, which the Examiner equates to the annular continuous sealing zone of the present invention, only projects beyond a portion of the film layer 16 due to the curvi-linear shape of the film layer 16. Thus, this left-most “hump” of the distal end 28 or the annular continuous sealing zone of Moriaki does not project beyond a surface of the entire edge region of the film layer 16, as is recited in amended claim 15.

Furthermore, Moriaki fails to disclose that the distal end 28, or the uncoated sealing section as asserted by the Examiner, has at least two continuous sealing lips on its outer circumference spaced-apart by a continuous recess 12 in combination with an annular continuous sealing zone projects slightly radially beyond a surface of the entire edge region of the inner film, as is recited in amended independent claim 15. Instead, as asserted by the Examiner in the Interview Summary Form and as shown in the diagram of Moriaki above, the left most “hump” of the distal end 28 is equivalent to the annular continuous sealing zone 13 of the present

invention. Even assuming, *arguendo*, that this interpretation is proper, Figure 12 of Moriaki then does not disclose both an annular continuous sealing zone and at least two continuous sealing lips on an outer circumference on the uncoated sealing section that are spaced-apart by a continuous recess. Alternatively, if the Examiner asserts that the two “humps” of Moriaki are equivalent to the at least two continuous sealing lips of amended independent claim 15, then Moriaki does not disclose an annular continuous sealing zone projecting slightly radially beyond a surface of the entire edge region of the inner film, as is recited in amended independent claim 15.

Based upon each of the above, Moriaki fails to disclose each and every element of independent claim 15 of the present application. Claims 17-20 are dependent upon independent claim 15, as amended. Thus, Applicant respectfully submits that claims 15 and 17-20 are not anticipated by Moriaki and requests that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Amended Claim 19

Claim 19, which depends from independent claim 15, has been amended more particularly to point out that the receiving cavity (6) has a bottom (6b) having a first diameter and a receiving orifice having a second diameter, the second diameter being larger than the first diameter. In contrast, as seen in Fig. 12, the inner most surface or bottom of the opening 23 of the device of Moriaki has the same diameter as the outer most surface or top at the opposite end of the opening 23. Thus, the first diameter of the opening 23 is the same as the second diameter of the opening 23. Further, none of the other embodiments of Moriaki discloses a receiving cavity having a bottom with a first diameter and a receiving orifice with a second diameter, wherein the second diameter is larger than the first diameter, as is recited in amended claim 19.

Based on the above, Applicant respectfully submits that Moriaki fails to disclose each and every element of dependent claim 19. Thus, Applicant respectfully submits that amended claim 19, which depends upon independent amended claim 15, is not anticipated by Moriaki and requests that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

New Claims 21-26

New independent claim 21 of the present application is directed to a pharmaceutical piston stopper and recites as follows:

a base body having a cavity formed therein, wherein the base body includes:

- a piston section, proximate a first end of the base body, completely covered with an inert film coating, and an uncoated sealing section, proximate a second end of the base body, the uncoated sealing section including:
 - a first portion having at least two continuous sealing lips forming a seal on its outer circumference, the two lips being spaced-apart by a continuous recess, and
 - a second portion having a generally flat side profile projecting slightly radially beyond a surface of the entire edge region of the inert film,

wherein the second portion is positioned between the first portion and the piston section.
[Emphasis added]

Applicant respectfully submits that Moriaki, and every other prior art reference currently of record, fails to disclose, teach, or even suggest each and every element of new independent claim 21. Specifically, no prior art reference currently of record discloses a piston section completely covered with an inert film and an uncoated sealing section having a first portion with at least two continuous sealing lips spaced-apart by a continuous recess and a second portion having a generally flat side profile projecting radially beyond a surface of the entire edge region of the inert film, as is recited in new independent claim 21. Further, since no prior art reference currently of record discloses, teaches or even suggests the combined structure cited in new independent claim 21, Applicant respectfully submits that such a combination would not have been obvious to one of ordinary skill in the art at the time of the invention.

Based on the above, Applicant respectfully submits that none of the prior art references currently of record discloses each and every element of new independent claim 21. New claims 22-26 are dependent upon new independent 21. Accordingly, Applicant respectfully submits that new claims 21-26 are patentable over all of the references currently of record in the application and respectfully request allowance of claims 21-16.

Response to the Office Action of July 14, 2008
Application: 10/706,122

CONCLUSION

In view of the foregoing Amendment and Remarks, Applicant respectfully submits that the present application, including amended claims 15 and 17-26, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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November 13, 2008 By: _____
(Date)



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